REMARKS

Claims 4-11, 15-19, 21, and 25-30 remain in the application. Claims 2, 13, and 23 have been canceled.

Claims 1, 12 and 22 have been amended to specify a *plastic* container, support for which can be found in canceled claims 2, 13 and 23.

Claims 3, 14 and 24 have been amended to change claim dependencies and to specify "container" rather than "package," support for which can be found in Applicant's specification at page 26, line 8.

Claim 20 has been amended to correct a typographical error.

Invention Synopsis

The present invention is directed to a liquid nutritional formula, containing Vitamin D and extensively hydrolyzed protein with a degree of hydrolysis of at least about 20%, aseptically packaged in a plastic container, which results in a surprisingly reduced rate of Vitamin D degradation. The invention is also directed toward a method of making the formula.

Examiner Interview

Applicant's undersigned attorney gratefully acknowledges the telephonic interview granted by Examiner Pratt on November 28, 2006, during which the pending prior art rejections and cited references were discussed. Sandra Weida, Senior Scientist, Pediatric Research and Development, Abbott Laboratories, participated in the interview. The substance of the interview is embodied in the following remarks.

CLAIM REJECTIONS UNDER 35 USC 103(a)

Claims 1-30 have been rejected under 35 USC 103(a) as being unpatentable over Girsh (5,204,134) or Cope et al. (5,480,872) or Hill et al. (5,382,439) in view of Lien et al. (US 2004/0062849).

The Examiner contends that it would have been obvious to incorporate the hydrolyzed protein of Lien et al. (with a defined DH/degree hydrolysis) into the nutritional formulations disclosed by any one of Girsh, Hill et al., or Cope et al., to thereby realize the claimed invention. Applicant respectfully traverses this rejection as it would apply to the amended claims.

Applicant found, surprisingly, that the shelf-life stability of Vitamin D can be improved, even when formulated in the presence of extensively hydrolyzed protein, provided that the formula is aseptically packaged in plastic containers rather than retort packaged in metal containers (Applicant's specification, p. 3, lines 9-15). Among the vitamins evaluated, only Vitamin D showed significantly improved stability (Applicant's specification, p. 14, lines 22-24; pp. 24 and 25, Table VII). As amended, the claimed invention is not directed to *any* container, but only to an aseptically packaged *plastic* containers.

None of the references disclose the use of a plastic container. None disclose the use of such a container for an aseptically packaged composition containing extensively hydrolyzed protein. And therefore none disclose the vitamin D stability benefits made possible by such a combination.

Girsh discloses aseptic processing in the manufacture of a hypoallergenic milk comprising hydrolyzed protein. Although Girsh discloses aseptic packaging, he fails to disclose aseptically packaged *plastic* containers (col. 9, lines 15-18). The Examiner contends that it would have been obvious to use plastic and resealable unidose packages in the claimed process because they are commonly used. However, as noted above, in the present invention, it was unexpectedly found that when the claimed formula is aseptically packaged in a plastic container, Vitamin D shelf life stability is significantly improved.

Girsh is silent as to Vitamin D stability. Instead, Girsh actually teaches away from a reduction in Vitamin D degradation by teaching the use of water dispersible Vitamin D (col. 10, lines 17 and 18) and the use of L-cysteine as a "preferred" amino acid (col. 7, lines 17-18). It is known in the art that fat soluble Vitamin D, when trapped within the fat portion of a composition, is less susceptible to degradation by free radical attack (see Hill et al., col. 12, lines 9-14). It is also known that the presence of cysteine (Hill et. al. col. 2, lines 24-30) induces Vitamin D degradation, typically by causing isomerization (Hill et. al. col. 2, lines 33-37).

As to the Hill et al. reference, although it teaches a method of improving the stability of Vitamin D, the improved stability is due to the addition of Vitamin C at concentrations exceeding 300 mg/L (col. 1, lines 10-14). The present invention, by contrast, improves vitamin D stability by aseptically packaging in plastic containers, not by relying upon the use of high Vitamin C concentrations. To that point, Hill only discloses preliminary heat treatment steps, not aseptic packaging (col. 3, lines 14-22).

The Lien et al. and Cope et al. references also fail to teach either aseptic plastic packaging or a reduction in the rate of Vitamin D degradation.

In short, none of the references, taken alone or in combination, disclose or suggest aseptic packaging for the purpose of reducing the rate of Vitamin D degradation in an extensively hydrolyzed protein formulation, and certainly none suggest the stability benefits made possible by Applicant's selection of a plastic package for such a formulation.

Conclusion

In view of the amendments presented and the foregoing remarks, Applicant respectfully requests reconsideration of this application, withdrawal of the rejections, and allowance of the pending claims.

Respectfully submitted,

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